## PREMIER DIRECTING.

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July 27, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204



RE: 21 U.S.C. Section 343(r)(6) Notification of Statements on Dietary Supplements

Dear Sir/Madam:

I hereby notify the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Uric Acid Formula, a dietary supplement. Premier Direct, Inc. is a manufacturer of Uric Acid Formula.

## Statements Being Made in the Labeling of Uric Acid Formula

- (1) Promote normal uric acid levels!
- (2) Uric Acid Formula can help regulate uric acid levels. This special nutritional support can assist the body's own ability to naturally lower uric acid levels.
- (3) Uric Acid Formula is a special natural formula that can help maintain stable uric acid levels
- (4) Celery (Apium graveolens) Has been shown to help keep uric acid levels down
- (5) Chiso (Perilla frutescens) Japanese researchers have found that this weedy mint contains fairly high levels of four compounds known as Xanthine Oxidase (XO) Inhibitors, which help prevent the synthesis of uric acid.
- (6) Pantothenic Acid (Vitamin B5) This vitamin may help to support healthy uric acid levels
- (7) Vitamin A This vitamin is believed to be essential for the lining of the urinary system
- (8) Vitamin E This vitamin supports the cells that produce uric acid

To the best of my knowledge, and based upon information and belief present at the time of executing this notice, I certify that this information is accurate and complete and Premier Direct, Inc. possesses substantiation that the statements are truthful and not misleading.

John Humel VP

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